

# PATENT COOPERATION TREATY

## PCT

### INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY



(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

REC'D 03 FEB 2006

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Applicant's or agent's file reference P2233PCT		<b>FOR FURTHER ACTION</b>		See Form PCT/PEA/416
International application No. PCT/US2004/022715		International filing date (day/month/year) 30.06.2004		Priority date (day/month/year) 22.09.2003
International Patent Classification (IPC) or national classification and IPC A61F5/01				
Applicant UNIVERSITY OF MARYLAND, BALTIMORE et al.				
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 5 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> sent to the applicant and to the International Bureau a total of 6 sheets, as follows:</p> <p style="margin-left: 40px;"><input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p style="margin-left: 40px;"><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>				
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the opinion</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input checked="" type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>				
Date of submission of the demand  18.07.2005		Date of completion of this report  01.02.2006		
Name and mailing address of the international preliminary examining authority:   European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465		Authorized Officer  Josten, S  Telephone No. +49 89 2399-2338  		

**INTERNATIONAL PRELIMINARY REPORT  
ON PATENTABILITY**

International application No.  
PCT/US2004/022715

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**Box No. I Basis of the report**

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1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
  - ☐ publication of the international application (under Rule 12.4)
  - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements\*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

**Description, Pages**

1-18 as originally filed

**Claims, Numbers**

1-33 received on 20.08.2005 with letter of 18.07.2005

**Drawings, Sheets**

1/4-4/4 as originally filed

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing (*specify*):
- ☐ any table(s) related to sequence listing (*specify*):

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing (*specify*):
- ☐ any table(s) related to sequence listing (*specify*):

\* If item 4 applies, some or all of these sheets may be marked "superseded."

**INTERNATIONAL PRELIMINARY REPORT  
ON PATENTABILITY**

International application No.  
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**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

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1. Statement

Novelty (N)	Yes: Claims	1-33
	No: Claims	
Inventive step (IS)	Yes: Claims	1-33
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1-33
	No: Claims	

2. Citations and explanations (Rule 70.7):

**see separate sheet**

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**Box No. VII Certain defects in the international application**

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The following defects in the form or contents of the international application have been noted:

**see separate sheet**

**Re Item V**

**Reasoned statement with regard to novelty, inventive step or industrial applicability;  
citations and explanations supporting such statement**

1. The document US-A-3680549 (=D1) is regarded as being the closest prior art to the subject-matter of claim 1 and shows (the references applying to this document):

An orthosis comprising a single, unitary body, the unitary body comprising:  
a generally spiral-shaped lower leg portion 14 that, when the orthosis is worn, covers at least a portion of the anterior surface of the wearer's lower leg and at least a portion of the posterior surface of the wearer's lower leg, and  
a foot plate portion 12 that, when the orthosis is worn, accepts the wearer's foot, wherein the lower leg portion is configured to spiral upward from the foot plate portion (see figures 1 and 2 of D1).

The subject-matter of claim 1 differs from this known orthosis in that the unitary body is made of composite carbon fiber and that the lower leg portion makes contact with an anterior surface of the wearer's lower leg prior to making contact with a posterior surface of the wearer's lower leg as the lower leg portion ascends.

The above-mentioned different features solve the problem of transferring mechanical energy during walking so as to simultaneously stop the knee from hyper-extending during the stance phase by generating a knee flexion moment while maintaining the foot in a position that allows the heel to contact the ground first at heel strike. These different features cannot be derived from the available documents.

Thus, claim 1 meets the requirements of Articles 33(2) and 33(3) PCT.

2. Claims 2 to 33 are dependent on claim 1 and as such also meet the requirements of the PCT with respect to novelty and inventive step.

**INTERNATIONAL PRELIMINARY  
REPORT ON PATENTABILITY  
(SEPARATE SHEET)**

International application No.

**PCT/US2004/022715**

**Re Item VII**

**Certain defects in the international application**

3. The independent claim should have been properly cast in the two-part form, with those features which in combination are known from D1 being placed in the preamble (Rule 6.3(b) PCT).
4. Reference signs in parentheses should have been inserted in the claims to increase their intelligibility. This applies to both the preamble and characterising portion (Rule 6.2(b) PCT).
5. The application does not meet the requirements of Rule 5.1(a)(ii) PCT since document D1 should have been cited in the description and the relevant background art disclosed therein should have been briefly discussed.

1. An orthosis comprising a single, unitary body made of composite carbon fiber, the unitary body comprising:

a generally spiral-shaped lower leg portion that, when the orthosis is worn, covers at least a portion of the anterior surface of the wearer's lower leg and at least a portion of the posterior surface of the wearer's lower leg; and

a foot plate portion that, when the orthosis is worn, accepts the wearer's foot, wherein the lower leg portion is configured to spiral upward from the foot plate portion and make contact with an anterior surface of the wearer's lower leg prior to making contact with a posterior surface of the wearer's lower leg as the lower leg portion ascends.

2. The orthosis of claim 1, wherein the foot plate portion comprises:

an anterior section; and

a posterior section,

wherein, when the orthosis is worn, the wearer's toes contact the anterior section and the wearer's heel contacts the posterior section.

3. The orthosis of claim 1 or 2, wherein:

the unitary body transfers mechanical energy while the wearer is walking;

the unitary body uses the transferred mechanical energy to stop the wearer's knee from hyperextending; and

the unitary body maintains the wearer's foot in a position that allows the heel of the person's foot to contact the ground before the rest of the wearer's foot.

4. The orthosis of one of claims 1-3, wherein the lower leg portion comprises an ascending section that extends from the foot plate section and curves toward the anterior surface of the wearer's lower leg to form a shin section.

5. The orthosis of one of claims 1-4, wherein, from the shin section, the lower leg portion continues to spiral around at least a portion of a lateral surface of the wearer's lower leg and transitions into a calf section.
6. The orthosis of one of claims 1-5, wherein the calf section terminates in an upper end of the lower leg portion and begins to spiral back toward the anterior surface of the wearer's lower leg.
7. The orthosis of one of claims 1-6, wherein the angle at which the lower leg portion spirals upward gradually decreases as the lower leg portion nears the calf of the wearer.
8. The orthosis of one of claims 1-7, wherein the foot plate portion is generally contoured to complement at least a portion of the plantar surface of the wearer's foot so as to permit the wearer to wear shoes or sandals.
9. The orthosis of one of claims 1-7, wherein the unitary body comprises:  
an inner surface; and  
a lining material attached to the inner surface.
10. The orthosis of claim 9, wherein the lining material is removably attached to the inner surface.
11. The orthosis of claim 9, wherein the lining material is removably attached to the inner surface using Velcro™.
12. The orthosis of one of claims 1-7, wherein the unitary body is made of composite carbon fiber.
13. The orthosis of one of claims 1-7, wherein the lower leg portion comprises a section that extends from the foot plate section.



14. The orthosis of claim 13,  
wherein the foot plate section comprises a posterior section, and  
wherein the section that extends from the foot plate section is disposed at about 1/4 of the length of the foot plate section from the posterior section.
15. The orthosis of one of claims 1-7,  
wherein the foot plate portion and the lower leg portion are disposed at an angle with respect to one another, and  
wherein the difference between the angle and 90 degrees is between about 7 degrees and about 14 degrees.
16. The orthosis of one of claims 1-7,  
wherein the foot plate portion and the lower leg portion are disposed at an angle with respect to one another, and  
wherein the difference between the angle and 90 degrees is between about 9 degrees and about 12 degrees.
17. The orthosis of one of claims 1-7,  
wherein the foot plate portion and the lower leg portion are disposed at an angle with respect to one another, and  
wherein the difference between the angle and 90 degrees is about 10 degrees.
18. The orthosis of one of claims 1-7,  
wherein the foot plate portion and the lower leg portion are disposed at an angle with respect to one another, and  
wherein the difference between the angle and 90 degrees is between about 20 degrees and about 25 degrees.
19. The orthosis of one of claims 1-7,  
wherein the foot plate portion and the lower leg portion are disposed at an angle with respect to one another, and



wherein the difference between the angle and 90 degrees is between about 9 degrees and about 12 degrees.

20. The orthosis of one of claims 1-7,  
wherein the foot plate portion comprises a front edge and a back edge,  
wherein the back edge is elevated above the front edge.
21. The orthosis of one of claims 1-7,  
wherein the foot plate portion comprises a front edge and a back edge,  
wherein the distance between the back edge and ground level is about twice the distance between the front edge and ground level.
22. The orthosis of one of claims 1-7,  
wherein the foot plate portion comprises a front edge and a back edge,  
wherein the distance between the back edge and ground level is about 1 inch and the distance between the front edge and ground level is about 1/2 inch.
23. The orthosis of one of claims 1-7,  
wherein the foot plate portion comprises an anterior section and a posterior section,  
wherein the difference in elevation between the anterior section and the posterior section is greater than 0 centimeters and no greater than about 3 centimeters.
24. The orthosis of one of claims 1-7,  
wherein the foot plate portion comprises an anterior section and a posterior section,  
wherein the difference in elevation between the anterior section and the posterior section is between about 1.7 centimeters and about 2.3 centimeters.
25. The orthosis of one of claims 1-7,

wherein the foot plate portion comprises an anterior section and a posterior section,

wherein the difference in elevation between the anterior section and the posterior section is about 2.

26. The orthosis of one of claims 1-7,

wherein the foot plate portion comprises an anterior section and a posterior section,

wherein the difference in elevation between the anterior section and the posterior section is between about 1 centimeter and about 1.5 centimeters.

27. The orthosis of one of claims 1-7,

wherein the foot plate portion comprises an anterior section and a posterior section,

wherein the difference in elevation between the anterior section and the posterior section is between about 2.5 centimeters and about 3 centimeters.

28. The orthosis of one of claims 1-7,

wherein the foot plate portion comprises a medial side and a lateral side,

wherein the difference in elevation between the medial side and the lateral side is greater than 0 millimeters and no greater than about 10 millimeters.

29. The orthosis of one of claims 1-7,

wherein the foot plate portion comprises a medial side and a lateral side,

wherein the difference in elevation between the medial side and the lateral side is between about 2 millimeters and about 3 millimeters.

30. The orthosis of one of claims 1-7,

wherein the foot plate portion comprises a medial side and a lateral side,

wherein the difference in elevation between the medial side and the lateral side is between about 5 millimeters and about 7 millimeters.

31. The orthosis of one of claims 1-7,  
wherein the foot plate portion comprises a medial side and a lateral side,  
wherein the difference in elevation between the medial side and the lateral side is  
between about 8 millimeters and about 10 millimeters.
32. The orthosis of one of claims 1-7,  
wherein the foot plate portion comprises a medial side and a lateral side,  
wherein the difference in elevation between the medial side and the lateral side is  
greater than 0 millimeters and no greater than about 1 millimeter.
33. The orthosis of one of claims 1-7, wherein the foot plate portion has a  
substantially flat outer surface.

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